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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,220	03/17/2004	Masaki Sunami	227833	3562

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EXAMINER	
PAGONAKIS, ANNA	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,220	SUNAMI ET AL.	
	Examiner	Art Unit	
	ANNA PAGONAKIS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9; 11-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/2005, 8 sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-9; 11-23 are presented for examination.

Applicant's Amendment filed on 1/25/2008 has been received and entered into the present application. References not found from the Information Disclosure Statement (IDS) filed on 1/25/2008 have been received and entered into the present application. As reflected by the attached, completed copy of form PTO-1449, the Examiner has considered the cited references.

Claims 1-9; 11-23 remain currently under examination. Claims 2-5, 9, and 15 are currently amended. Claim 10 is withdrawn.

Given that examination has proceeded already in the previous Office Action beyond the elected cardiovascular disorder of hyperlipidemia, the specie election regard the type of cardiovascular disorder is withdrawn thus including all instantly cited cardiovascular disorders as being now under examination.

Applicants arguments, filed 1/25/2008, have been fully considered. Rejection not reiterated from the previous Office Action is hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly

owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9; 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gumkowski et al (US PGPUb 20060014788, already of record) in view of Ault et al (US Patent 7,049,283, already of record) and Englert et al (US 6,723,751, already of record).

Applicant traverses the instant rejection, stating that has failed to present a prima facie case of obviousness. Applicant alleges that the Office has not pointed to anything in either cited reference to indicate why one would combine the two disclosures and further states that Ault et al. is not directed to the use of CETP inhibitors or cardiovascular diseases. Applicant submits that, in contrast, Ault et al. teaches a formulation useful for the treatment of bone related diseases and calcium disorders (Applicants remarks, p. 15). Finally, Applicant alleges that Examiner has failed to describe why one would knowingly select a compound of Formula I from Gumkowski et al. and combine with a water-insoluble concentration-enhancing additive such as crospovidone.

Applicant's traversal has been fully and carefully considered in its entirety, but fails to be persuasive.

The examiner contends that the level of skill in the art is evident from the references and what is lacking from each of the references in the analysis of the Office Action. Further, the examiner has explained the reason for motivation (page 9-10 of previous Office Action).

Moreover, Applicant's traversal is Ault et al. teaches a formulation comprising crospovidone for the treatment of other diseases. This is found pertinent given that the reference is used to teach the use of crospovidone to aid an increase in the bioavailability of an active agent. Applicant argues there is no

motivation to combine, however, as recited in the Office Action mailed on 10/26/2007, "it would be obvious to one in the art to combine the substance that results in the increased bioavailability (crospovidone) to another substances in need of becoming more bioavailable (elected compound)." Please refer to the previous Office Action for the entire context of the rejection.

Claim 2 has been amended to "more than 50 percent of the cholesteryl ester transfer protein inhibitor". Gumkowski et al. teach the CETP inhibitor in a range of 1 to 5 percent (paragraph [0049]). A prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties (MPEP 2144.05).

Further, claims 2-6, 12 is drawn to the elected compound and crospovidone in crystalline form. This would have been obvious. Englert et al. (of record) teaches a crystalline form of a benzamide and processes for their preparation, their use, and pharmaceutical preparations comprising them (abstract). Given the benzamide structure of the claimed compound it would have been obvious to utilize the crystallization techniques outlined in Englert et al. to achieve a crystalline product/formulation.

Also, the "about" limitation in claims 7-13 encompasses thereby any functional amount provided that the remainder of the claim embodiment limitations are anticipated by the prior art reference.

Regarding, claims 18-23, it is the Examiner's position that the instantly claimed method is inherently taught by the reference. It is noted that In re Best (195 USPQ 43) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column first full paragraph). There is no requirement that person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior

art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1669 (Fed. Cir. 2004). ("[T]he fact that a characteristic is a necessary feature or result of a prior art embodiment (that it itself sufficiently described and enabled) is enough for inherent anticipate, even if that fact was unknown at the time of the prior invention"). The concentration of the cholesteryl ester transfer protein inhibitor present in the bloodstream are inherently determined by the particular drug/medication.

Consequently, Applicant's arguments fail to clearly point out the patentable novelty which he thinks the claims present in view of the state of the art disclosed by the reference cited. In addition the arguments also fail to specifically point out disagreements with the Examiner's contentions and/or how the claims avoid the reference or are distinguishes from the same and are, therefore, clear not persuasive in establishing the evidence of novelty outweighs that proffered to support the instant conclusion of a lack of novelty.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg,* 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman,* 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Long{* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum,* 686 F.2d 937, 214 USPO 761 (CCPA 1982); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b}.

Claims 1-9; 11-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,753,346 (Shinkai et al.) in view of Ault et al (US Patent 7,049,283).

Although the conflicting claims are not identical, they are not patentably distinct from each other because in practicing the instantly claimed methods of increasing bioavailability; increasing the extent of absorption or treating a cardiovascular disease such as hyperlipidemia, one would necessarily have to be practicing the claimed subject matter of '346 patent because the '346 claims are directed to the same compound as utilized in the presently claimed subject matter, e.g., see claims 1-7 of the '346 patent. Further, claims 16 and 17 of the '346 patent in fact, cite a method of treating hyperlipidemia.

Ault et al. teaches a composition suitable for oral delivery of pharmacologically active agents, comprising a therapeutically effective amount of a pharmacologically active agent; a crospovidone or povidione; and a delivery agent for said pharmacologically active agents (abstract). Furthermore, the reference teaches that the composition containing crospovidone versus the comparative compositions which do not contain crospovidone, resulting in greatly enhanced oral bioavailability of the formulations according to the instant invention (column 9, lines 34-38).

It is obvious from the above teachings of '346 patent that it expressly contemplates variation in the dosage amounts and schedule of the active agents and specifically acknowledges that such a matter was well within the skill of the artisan at the time of the invention and would not have required undue experimentation or have been outside the realm of knowledge generally available to the skilled artisan. Factors that would have been taken into consideration when making such a determination would have included, but not have been limited to, the age, weight, sex, diet and medical condition of the patient, severity of the disease, route of administration, pharmacological considerations, e.g., activity, efficacy,

pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the dosage regimen and/or schedule of administration that would have actually been employed would have been expected to vary widely and, in the absence of evidence to the contrary, would not have been inconsistent with that which is presently claimed.

The functional amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of Applicant's invention.

Accordingly, for the above reasons, the claims are deemed properly rejected.

Conclusion

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614